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doi:10.1016/j.jvs.2008.05.086

Reply

We appreciate the interest of the readers above in our study analyzing the association of statins with mortality after infrainguinal bypass in patients with critical limb ischemia. Their insightful comments point to a weakness inherent to all nonrandomized studies—propensity score models or multivariable regression models can only control for measured confounders and not unmeasured confounders. Our study did not control for cholesterol levels, because these values were not available from our source data (the PREVENT III trial).

While we agree with the readers that there is a small body of literature, primarily pertaining to general surgery, that has suggested a potential benefit to hypercholesterolemia, this effect has yet to be demonstrated in patients with peripheral arterial disease. Nonetheless, our data do not allow us to refute the comments of the readers above—it is possible that, in our study, some of the mortality benefit that was attributed to the use of statins may have been affected by concurrent hypercholesterolemia in the patient group on statin therapy.

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doi:10.1016/j.jvs.2008.07.069

Carotid artery stenting: a promising therapeutic option for carotid artery stenosis or a bubble about to burst?

A recent prospective randomized trial compared for the first time the long-term results of carotid endarterectomy (CEA) with carotid artery stenting (CAS) (median observation time: 64 ± 12.1 months vs. 66 ± 12.1 months, respectively).[1] This study showed that CEA is superior to CAS with respect to stroke (0 of 42 vs. 4 of 42, respectively), >70% restenosis (0 of 29 vs. 6 of 32, respectively) and re-intervention rates (0 of 29 vs. 5 of 32, respectively; for all associations $P < .05$).[1]

Two issues may hamper the interpretation of the results of this study:[1] first, CAS was performed without the use of embolic protecting devices (EPDs).[1] Although the exact role of EPDs in CAS has not yet been established, their use may offer considerable advantages. For example, a large (n = 1,483 patients), multicenter (n = 26 hospitals), randomized study comparing CAS with vs. without EPDs demonstrated that, compared with non-use, the use of EPDs during CAS was associated with lower ipsilateral stroke (4.1% vs. 1.7%, respectively; $P = .007$) and lower non-fatal stroke and death rates (4.9% vs. 2.1%, respectively; $P = .004$).[2] Opposing results were reported in a recent prospective randomized study comparing the incidence of embolic lesions during CAS with vs. without EPDs;[3] the use of EPDs during CAS did not reduce the number of emboli (average number of embolic lesions: 6.1 vs. 6.2, respectively; $P = .79$).[3] A possible explanation for this lack of difference may be the small size of CAS procedures included (n = 36).[3]

A second drawback is the early recruitment period (August 1999 to April 2002).[1] Since then, the technique of CAS has evolved considerably; new, better-designed, and improved stent models have been introduced and employed. Additionally, physicians have gradually become more experienced; a study presenting a detailed analysis of periprocedural complications of CAS demonstrated the importance of an appropriate learning curve before systematic use of CAS.[4] Thus, it could be expected that a similar study performed today might produce different results than the ones reported.[1]

The role of CAS in the treatment of carotid artery stenosis is still the subject of extensive debate. Current evidence suggests that it may still be premature to attempt to draw definite conclusions.

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Submitted Jul 14, 2008; accepted Jul 15, 2008.

doi:10.1016/j.jvs.2008.07.078

Reply

Thank you for the opportunity to respond to the letter concerning our article "Alert for increased long-term follow-up after carotid artery stenting: Results of a prospective, randomized, single-center trial of carotid artery stenting vs carotid endarterectomy."

Carotid endarterectomy (CEA) or carotid artery stenting (CAS) in symptomatic patients is performed to reduce the risk of secondary stroke or stroke-related death. Therefore, the main focus of this article was the evaluation of restenosis, secondary stroke rate, and death in a long-term follow-up of a prospective, randomized study of CEA vs CAS.

We understand the concern that embolic protection devices (EPD) might reduce peri-interventional stroke rates after CAS. However, the cited publication[1] is not a randomized study but rather a registry from multiple cardiology centers during 1998 to 2003. The use of embolic protection devices (EPD) increased over

the years to 100% in 2003, and the comparison is a retrospective cohort analysis. The decision to treat or not to treat was left to the interventionist, who was not a neurologist. Along with other methodologic drawbacks, such as only registration of the complication rate during the hospital stay, any conclusion in comparison with our article should not be drawn.

The short-term results of our study revealed no difference between CAS and CEA (one vs no stroke, Table III). Importantly, however, there are no reports that EPDs are able to reduce secondary stroke rates on the long term. There is strong evidence that the reported stroke rates of four in 42 after CAS vs none in 42 after CEA in the long-term follow-up from our study correlate with the higher incidence of restenosis, and not with whether EDPs were used.

It is also notable that the study was performed in a high-volume center in Germany with very experienced surgical and interventional physicians. No residual stenosis was left after the primary procedure, and the intervention was performed with a low peri-interventional complication rate (Table III). An influence of a learning curve can be excluded. We admit that the exclusive use of the carotid Wallstent (Boston Scientific, Watertown, Mass) might influence the results of this study. However, this was extensively discussed in the second paragraph on page 97. Unfavorable results of prospective randomized trials should not be questioned with a remark that new devices might be more beneficial.

Most recent data of the SPACE (Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy) study, which was randomized until February 2006 and used different and "better designed and improved" stent types, support our findings. In the 1-year follow-up, a twofold higher restenosis rate of >8% was observed after CAS vs CEA (Prof. Dr. H. Eckstein, personal communication). These data confirm our conclusion that CEA seems to be superior to CAS concerning the development of restenosis and that ongoing trials have to gather long-term data including restenosis and reintervention rates as well as secondary stroke rates and survival.

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doi:10.1016/j.jvs.2008.07.077

Regarding "Easy alternatives to difficult clamping of distal vessels of the leg"

We have read with great interest the paper by August et al. Actually, the use of ordinary clamps can result in arterial damage, especially in endstage renal disease (ESRD) patients affected by critical limb ischemia (CLI).

Our group performed more than 1500 open distal arterial reconstructions of tibial and pedal arteries in CLI patients with tissue loss and gangrene (Rutherford 5-6). We used autologous material in 92% of grafts, preferably greater saphenous vein, followed by lesser saphenous and arm veins.[1,2] Comorbidities were diabetes 56%, clinically apparent coronary artery disease (CAD) 47%, previous aorto-coronary bypass graft (CABG) 8%, chronic obstructive pulmonary disease (COPD) 57%, chronic renal insufficiency 20%, and ESRD 10.4%.[3]

Finally, 164 limbs in ESRD patients with CLI were revascularized. The majority of these patients had a very diseased distal arterial network with heavily calcified arteries, poor run-off, and relevant comorbidities. Consequently, bypasses were more distal and technically demanding if compared to the standard CLI patients.[3] In our experience, as in others, renal insufficiency entailed a worse limb salvage ($P = .048$), and ESRD has been associated with significantly worse limb salvage ($P < .001$) and patient survival ($P = .011$).[4-6]

In this kind of patient, often distal arteries are not compressible due to extensive wall calcification.

For several years, by performing distal anastomosis, we have been putting a clamp only on the proximal part of the target vessel and we have been applying, as August et al, an intravenous cannula in order to occlude the distal end of the arteriotomy in tibial and plantar vessels. On the contrary to the authors, we did not cut the top of the cannula, but we did connect it by a 20-cm long plastic tube to a 30-mL syringe filled with heparinated (.20%) saline (Fig 1). The length of the tube has been useful to not hinder the suturing maneuvers. The whole system allowed a regular flushing with heparinated saline into the distal runoff, preventing thrombosis of the lumen in cases of poor retrograde bleeding. The size of cannulas varied between 18G and 24G according to the lumen of the artery.

Despite the caliber adaptation, in few cases it was not possible to move the cannula forward into the artery, because of the irregularity of the arterial wall. In these situations, we chose to clamp the artery only proximally to the arteriotomy, as we do in all cases, but not to clamp it distally at all. In order to minimize blood loss, we positioned the patient in an extreme Trendelenburg position, with the head raised to avoid discomfort, and we clamped the distal artery by gentle external digital compression (Fig 2). If the digital occlusion was ineffective due to stiffness of the arterial wall, we simply flushed the anastomosis area by pouring saline that flowed away with the blood thanks to the upraised position of the limb.

In conclusion, even though we agree with August et al about the advantage of the use of an intravenous cannula for distal arterial occlusion, we suggest the artifices we use since they critically

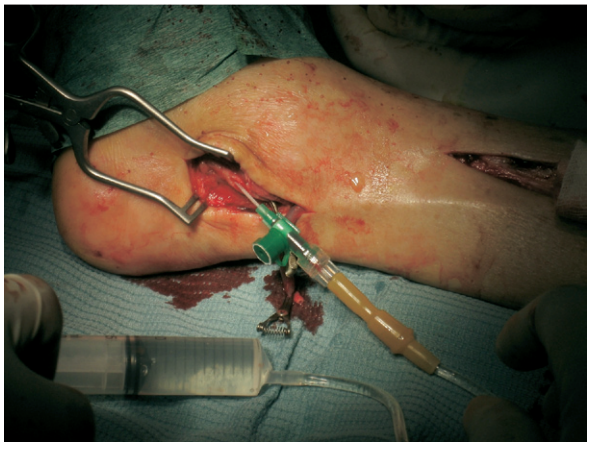

Fig 1. Intravenous cannula has been inserted into the plantar artery. The cannula has been connected to a syringe with heparinated solution.